DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Annexure – 15

	FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 4 and 5					
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APPLICATION ASSESSMENT CHECKLIST (ICH CTD – UPA AND IPA)

This Application Assessment Checklist should be used to ensure the submission of a complete dataset for Module 4 & 5 in the ICH Common Technical Dossier (ICH CTD) format and assessment report of Module 4 & 5 for UPA and IPA applications only. Colour scanned copies of the original documents should be submitted and original hard copies of documents are not required.

However, DGDA reserves the rights to request for the original or certified true copy of submitted documents if there is any doubt that a submitted scanned document is not an accurate reflection of the original document. The acceptance of the application after screening including assessment does not preclude requests by DGDA for additional documents or changes to the information/documents during evaluation.

This Checklist should be completed by checking each item against the dossier according to the application type.

Note:

- Cells with ☐ indicate that the documents shown are mandatory for the selected application type and evaluation route.
- Cells without ☐ indicate that the documents shown are not required for the selected application type and evaluation route.

Legend:

Application type	UPA	Unintroduced Product Application
	IPA	Introduced Product Application
	IND	Indigenous or locally developed
	IMP	Imported
Evaluation route	RT	Routine MA pathway
	EUA	Emergency Use Authorization

Product Name:

Application Date:

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Module 4 – Non-clinical Study Reports

Assessment Started on:

Section	Documents			Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
					UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
					RT	EUA	RT	EUA			Yes	No	NA	
4.1	Module 4 Table of Contents										☐	☐	☐	
4.2	Study Reports										☐	☐	☐	
	4.2.1	Pharmacology									☐	☐	☐	
		4.2.1.1	Primary Pharmacodynamics								☐	☐	☐	
		4.2.1.2	Secondary Pharmacodynamics								☐	☐	☐	
		4.2.1.3	Safety Pharmacology								☐	☐	☐	
		4.2.1.4	Pharmacodynamic Drug Interactions								☐	☐	☐	
	4.2.2	Pharmacokinetics			☐	☐	☐	☐	☐	☐	☐	☐	☐	
		4.2.2.1	Analytical Methods and Validation Reports								☐	☐	☐	
		4.2.2.2	Absorption								☐	☐	☐	
		4.2.2.3	Distribution								☐	☐	☐	
		4.2.2.4	Metabolism								☐	☐	☐	
		4.2.2.5	Excretion								☐	☐	☐	
		4.2.2.6	Pharmacokinetic Drug Interactions (non-clinical)								☐	☐	☐	

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Section	Documents			Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
					UPA		IPA		IND	IMP	Submitted?			
					RT	EUA	RT	EUA			Yes	No	NA	Assessment Outcome
4.2		4.2.2.7	Other Pharmacokinetic Studies		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	4.2.3	Toxicology									☐	☐	☐	
		4.2.3.1	Single-Dose Toxicity								☐	☐	☐	
		4.2.3.2	Repeat-Dose Toxicity								☐	☐	☐	
		4.2.3.3	Genotoxicity								☐	☐	☐	
		4.2.3.4	Carcinogenicity								☐	☐	☐	
		4.2.3.5	Reproductive and Developmental Toxicity								☐	☐	☐	
		4.2.3.6	Local Tolerance								☐	☐	☐	
		4.2.3.7	Other Toxicity Studies								☐	☐	☐	
4.3	List of Literature References										☐	☐	☐	

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Module 5 – Clinical Study Reports

Section	Documents	Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
			UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
			RT	EUA	RT	EUA			Yes	No	NA	
5.1	Module 5 Table of Contents		☐	☐	☐	☐	☐	☐	☐	☐	☐	
5.2	Tabular Listings of All Clinical Studies								☐	☐	☐	
5.3	Clinical Study Reports								☐	☐	☐	
	5.3.1 Reports of Biopharmaceutic Studies ▪ For EUA, information on the comparability between clinical trial (pivotal studies) and commercial formulations should be available in the Clinical Overview/Summary. If the commercial formulation for the Bangladesh market differs from the clinical trial formulation used in the pivotal studies, the final study report(s) of biopharmaceutic studies to establish bioequivalence between the commercial product formulation and the clinical trial formulation used in pivotal studies should be submitted. ▪ For RT, all biopharmaceutic study reports are required.											
	5.3.2 Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials								☐	☐	☐	
	5.3.3 Reports of Pharmacokinetic (PK) Studies								☐	☐	☐	

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Section	Documents		Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
5.3	5.3.4	Reports of Pharmacodynamic (PD) Studies		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	5.3.5	Reports of Efficacy and Safety Studies								☐	☐	☐	
		▪ For RT, study reports of ALL clinical trials (including the appendices and tables) should be submitted.								☐	☐	☐	
		▪ For EUA, study reports of pivotal or relevant clinical trials should be submitted (appendices and tables are required only upon request by DGDA).								☐	☐	☐	
		▪ The clinical trials should be conducted using the drug product formulation submitted in the application and in the appropriate patient population for the indication(s) and/or dosing regimen(s) as requested in the application.								☐	☐	☐	
		▪ If the commercial formulation for the Bangladesh market differs from the clinical trial formulation used in the pivotal studies, biopharmaceutic study reports are required (see section 5.3.1).								☐	☐	☐	

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Section	Documents		Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
				UPA		IPA		IND	IMP	Submitted?			
				RT	EUA	RT	EUA			Yes	No	NA	Assessment Outcome
5.3	5.3.5	▪ If the information on the comparability between the clinical trial formulation and the proposed commercial formulation is not available in the clinical study reports or the Clinical Overview/Summaries, a separate declaration letter should be submitted to confirm that the clinical trial formulation is the same as the commercial formulation proposed for registration in Bangladesh.								☐	☐	☐	
		▪ Phase III, confirmatory, randomised, controlled pivotal trials conducted in compliance with Good Clinical Practice (GCP) are required to support each requested indication and dosing regimen, unless adequately justified. Active-controlled studies should use relevant active comparators that are locally registered, unless adequately justified.		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	5.3.6	Reports of Post-marketing Experience								☐	☐	☐	
	5.3.7	Case Report Forms and Individual Patient Listings (required upon request by DGDA)								☐	☐	☐	
5.4	List of Key Literature References									☐	☐	☐	
5.5	Risk management plan (RMP) documents as separate attachment.									☐	☐	☐	
5.6	Other Supporting Documents									☐	☐	☐	

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Assessment Completed on		**Total Duration**	
Assessment Summary		**Assessment Done By/Date**	
Recommendation		**Head of Vaccine & Biologics Sign/Date**	

Issued by:

CONTROLLED COPY

ADMINISTRATION (DGDA)
MINISTRY OF HEALTH AND FAMILY WELFARE
BANGLADESH

Issue date: 10 NOV 2021

Note: 1. Estimated Time duration for Dossier assessment is 05 Months through Routine MA pathway.

2. Estimated Time duration for Dossier assessment is 05 days through EUA pathway.